

Clinical Visual Analytics for Review and Submission (CVARS)



Project Scope

Development of an open-source tool and package to enable generation of identified interactive plots for clinical review and direct inclusion in submissions to regulatory agencies. The initial scope is to develop a package to generate interactive forest and volcano plots for adverse events and FDA Medical Queries (FMQs) analysis outputs for inclusion in submissions to the FDA. This work is a collaboration among the American Statistical Association (ASA), PHUSE and the FDA.

Project Leads	Email
Melvin Munsaka, <i>Abbvie</i>	melvin.munsaka@abbvie.com
Jiang (Jessica) Hu, <i>FDA</i>	jiang.hu@fda.hhs.gov
Neetu Sangari, <i>Pragya Tech Leaders</i>	neetusang@gmail.com
Kerry Robson, <i>PHUSE Project Assistant</i>	kerry@phuse.global

Objectives & Deliverables

Timelines

An open-source R Shiny tool for generating the plots and associated outputs and an accompanying paper for the tool

Q3 2022

Complete manuscript

Q4 2024

Resources

[CVARS GitHub Page](#)

[CVARS](#)

CURRENT STATUS Q1 2024

- Participation at the CSS
- Presentation at the FDA